EPA's draft CUMULATIVE RISK SCREENING GUIDANCE

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Goals of Talk

- The Problem
- The Screening Process
  - Exposure assessment
  - Interactions
- Details about planning and scoping
  - Stakeholder involvement
- draft Cumulative Risk Screening document: Overview

Document Status: Internal Review Draft

The Problem

- Sites contaminated with 100's of chemicals
  - Potential exposure to others from offsite sources
- Analysts must identify those that matter
- Conventional assessments typically
  - evaluate single chemicals
  - may not thoroughly address chemical mixtures

Environmental Analysts' and Managers' Dilemmas

- Environmental processes: difficult to understand & predict
  - Huge complexity, variability, uncertainty
- Environmental management decisions: difficult to make
  - Many people with different values, many management goals
  - Uncertainty regarding best ways to achieve those goals

The man who insists upon seeing with perfect clearness before he decides, never decides.

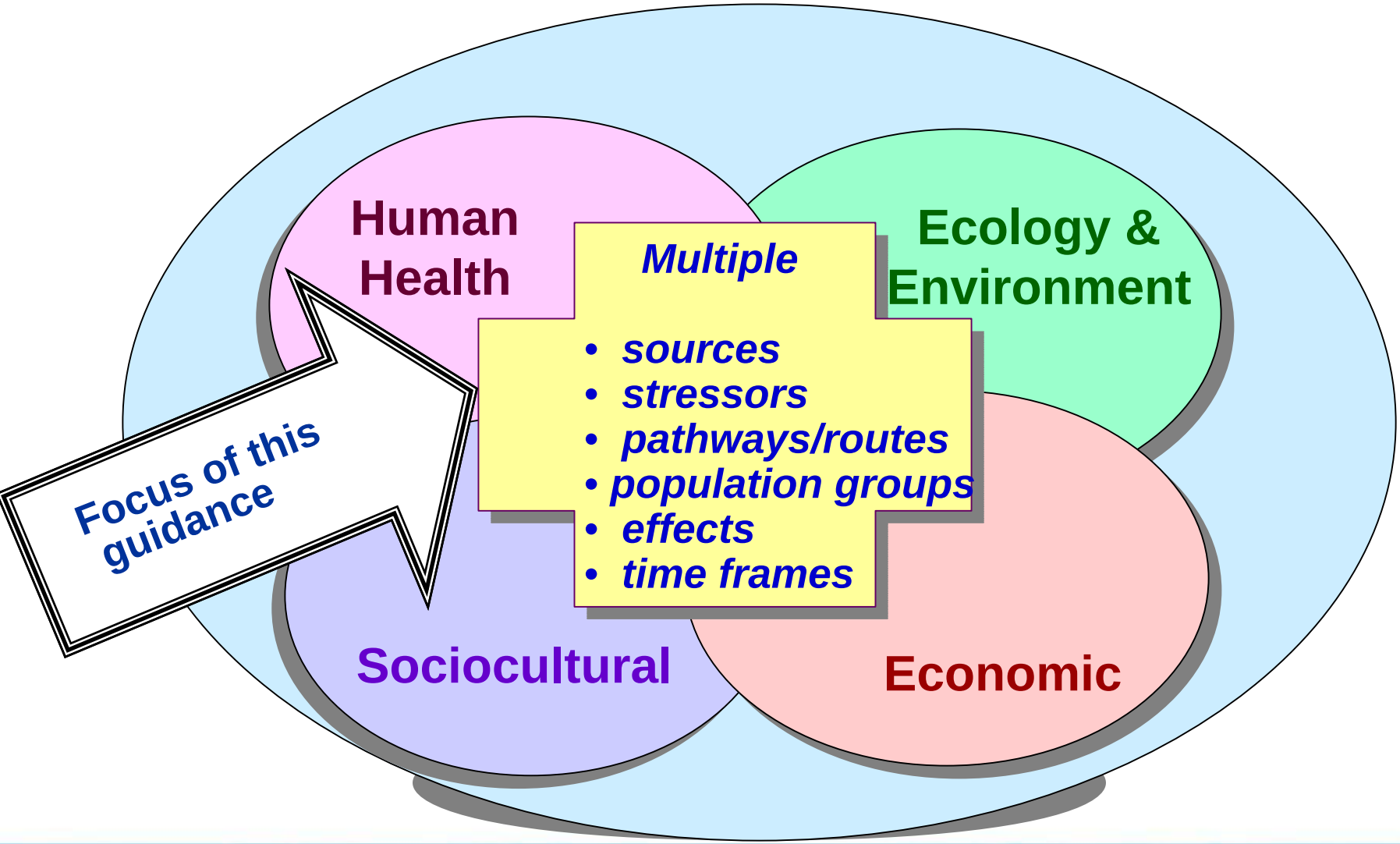
– Frederic Amiel

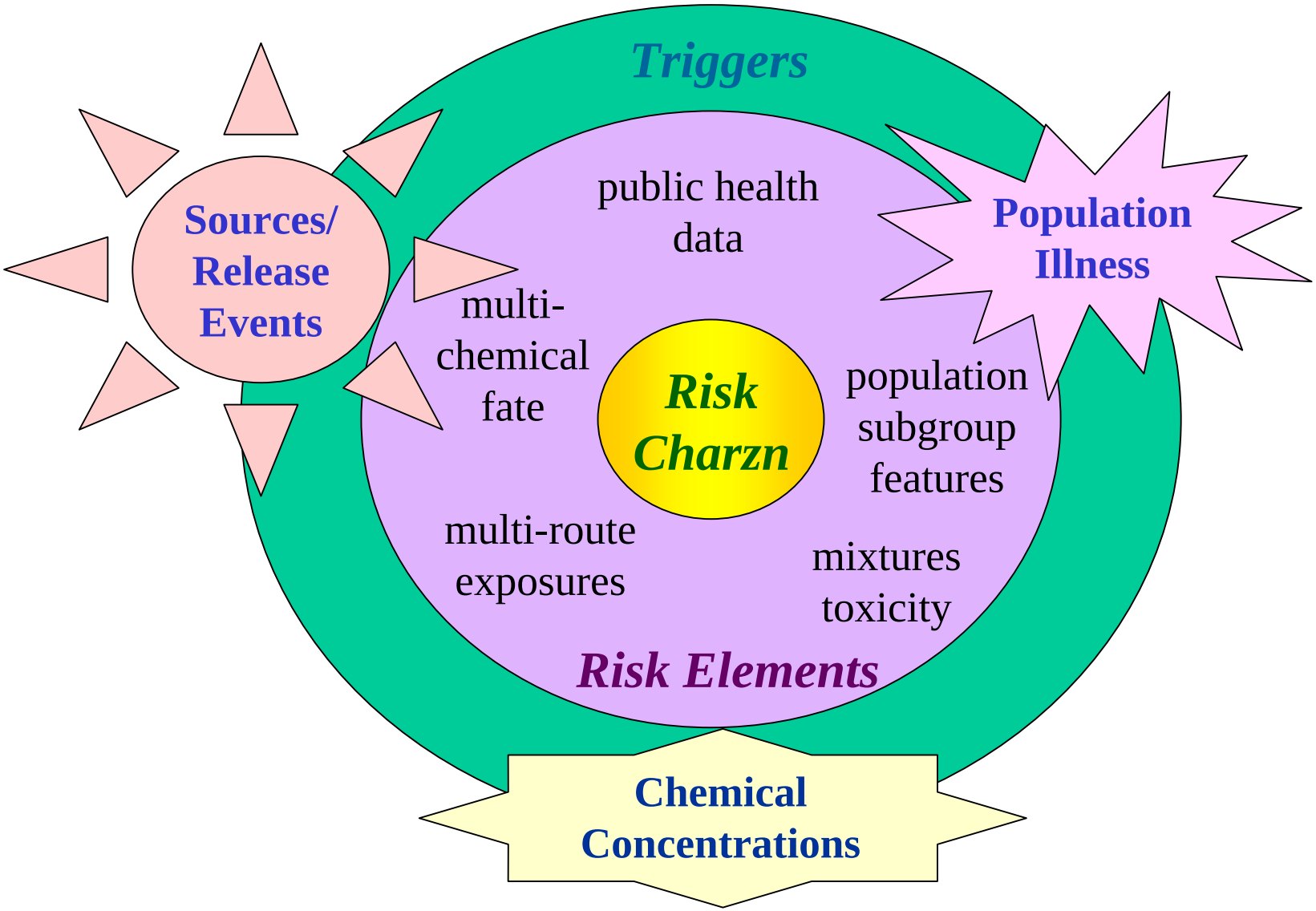
Why Write this Document?

- Support more informed decisions for managing potential health risks

- Demonstrate basic cumulative risk concepts with contaminated sites
- Capture “lessons learned” from successful community efforts

We're Assessing Risks of "Integrated Multiples"




Triggers
Sources/
Release
Events
public health
data
Population
Illness
multi-
chemical
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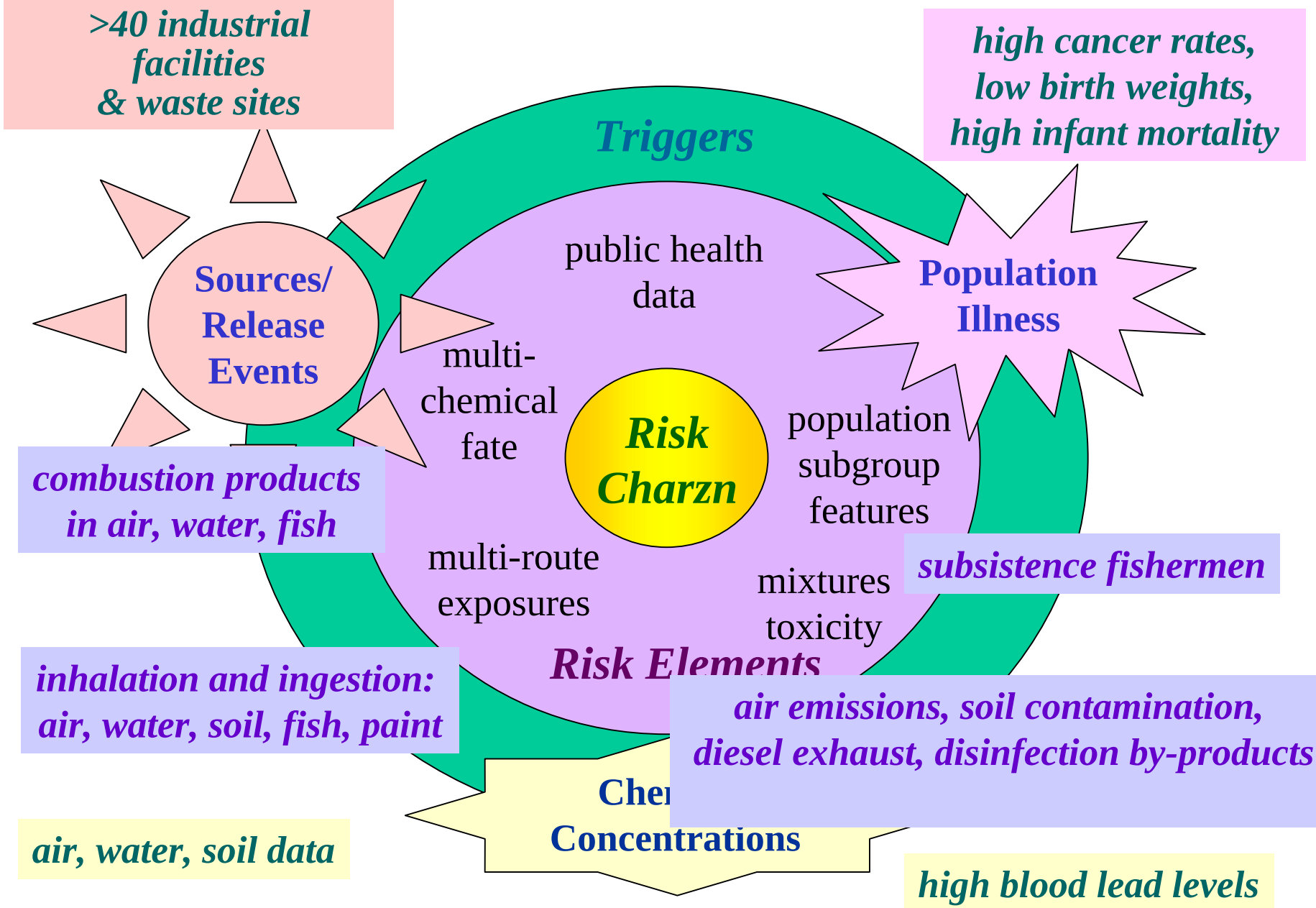
exposures
mixtures
toxicity
Risk Elements
Chemical
Concentrations


>40 industrial facilities & waste sites
high cancer rates, low birth weights, high infant mortality
Triggers
Sources/ Release Events
public health data
Population Illness
multi-chemical fate
Risk Charzn
population subgroup features
combustion products in air, water, fish
multi-route exposures
mixtures toxicity
subsistence fishermen
Risk Elements
inhalation and ingestion: air, water, soil, fish, paint
air emissions, soil contamination, diesel exhaust, disinfection by-products
Chei
Concentrations
air, water, soil data
high blood lead levels

Exposure Assessment Steps	
Characterize the exposure setting	Identify site environmental features and potential receptors
Identify potential exposure pathways	Describe sources, release mechanisms, receiving media, and locations for site chemicals
Quantify exposures by relevant routes	Estimate medium-specific chemical concentrations at points of human exposure, and calculate intakes (considering time, frequency, duration)

What's it mean to Screen?

Use of the Term Screening	
Overall relevance	Screen out if irrelevant to overall assessment
Enhanced evaluation	Screen into enhanced process, and further screen to group components with opportunity for interaction
Conservative assumptions	Apply bounding, default assumptions to screen out components clearly not of health concern. Health Protective Manner!

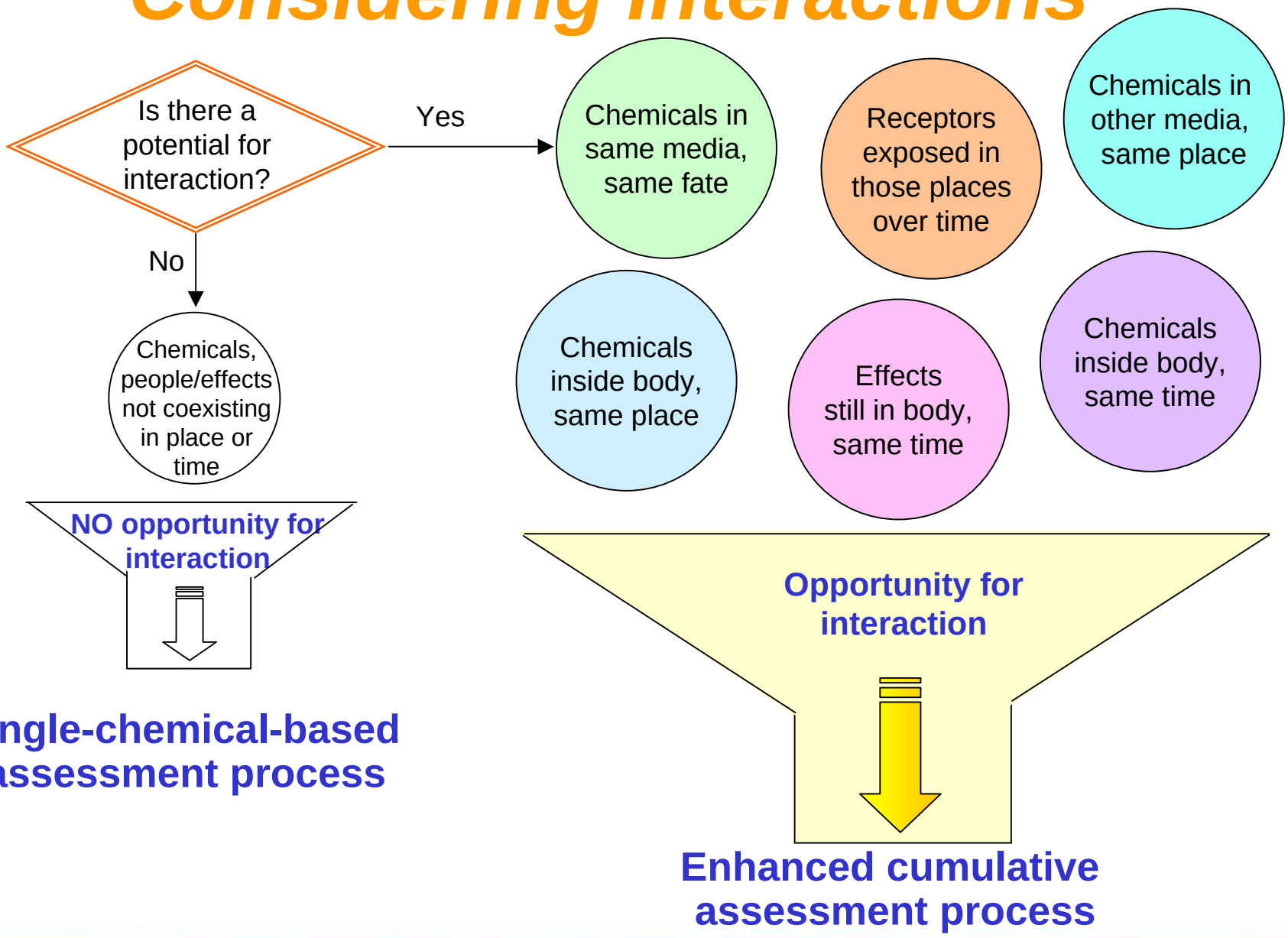
Accurately Focusing Resources on What Matters

"Screening" in Context of a Cumulative Exposure Assessment

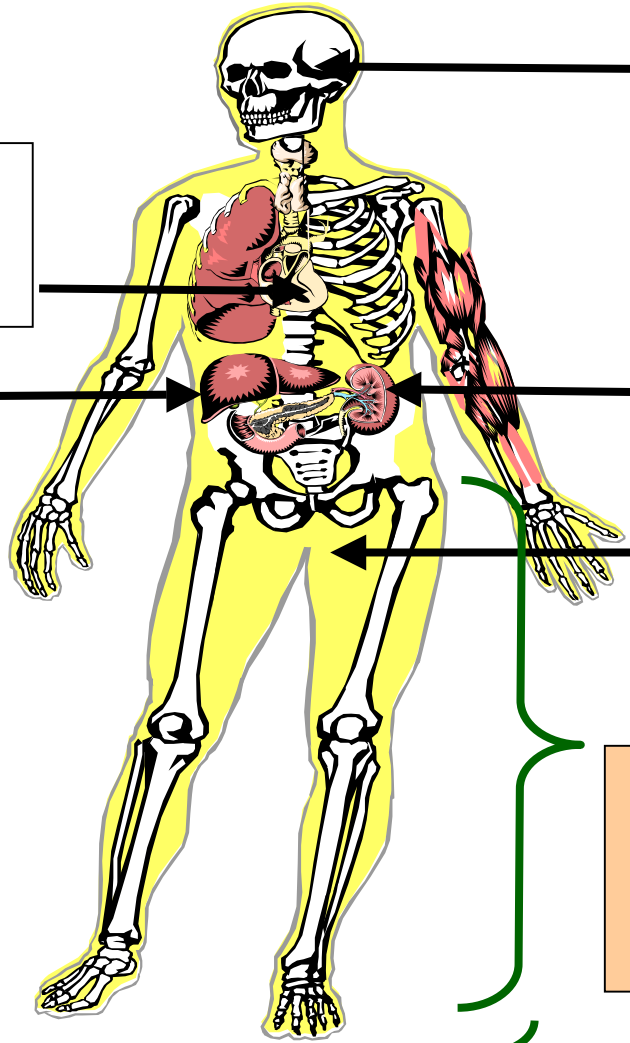
Exposure Assessment Questions
How can people be exposed to multiple site chemicals?
In which media, at what levels, where and when?
What could the amount of exposure be, for how long?
Are there any unique population susceptibility issues?

Comparison of Exposure Assessment Processes	
Basic Assessment	Enhanced Cumulative Assessment
What general question is being addressed?	
How are people exposed? how much?	Emphasize combined site contaminants and susceptible groups
What is evaluated?	
Site chemicals	Combined sources/releases (beyond site)
Individual chemicals	Emphasis on joint behavior, consider environmental interactions and grouped chemical sets
Concentrations at points of human contact	Emphasis on chemicals that “coexist”
“Representive” individuals and likely future land use	Include sensitive subgroups and unique exposure activities
Exposure routes for each chemical	Emphasis on combined chemicals across routes over time, consider exposure sequence

Considering Interactions



Primary Organs/Systems Affected Following Ingestion



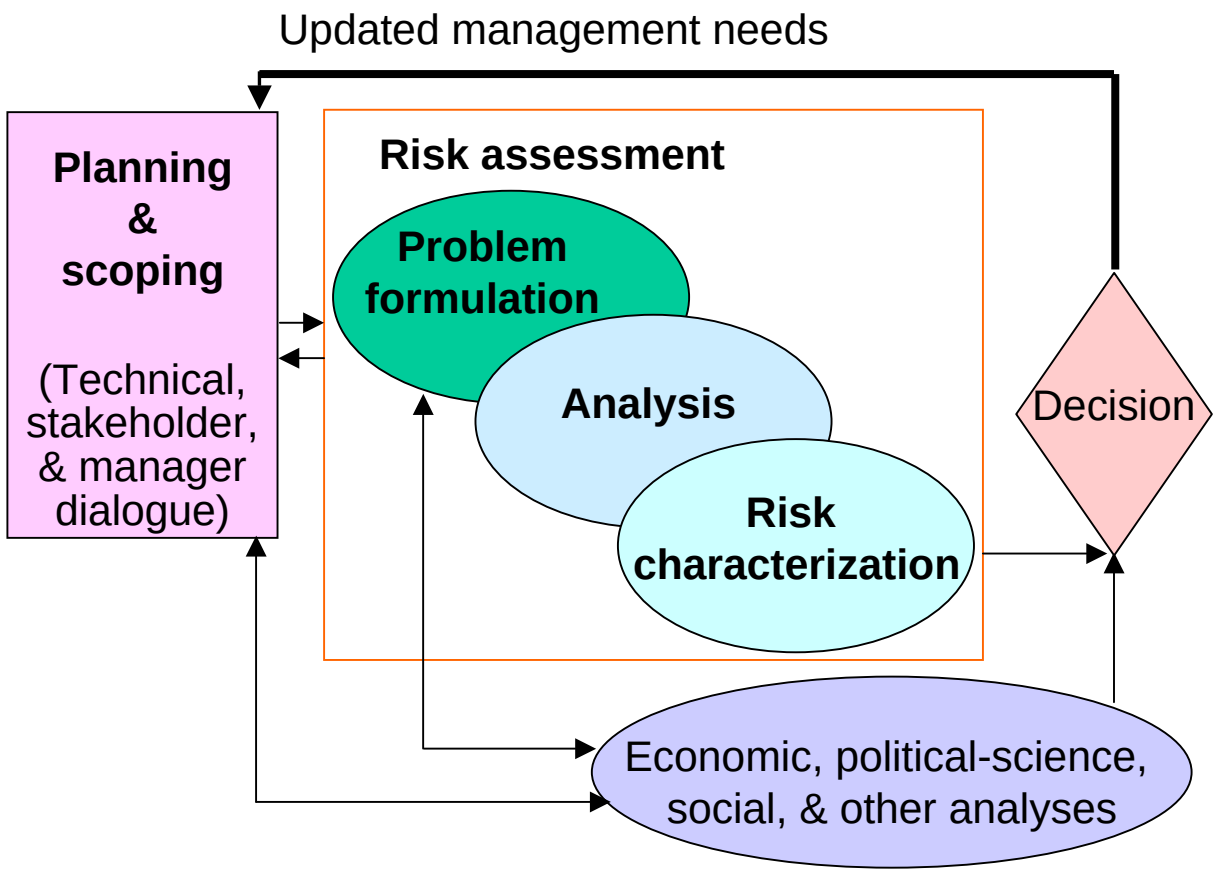
Cardiovascular system	Arsenic Cadmium Lead
Liver	Cadmium Chromium
Skin	**Arsenic**
Nervous system	Arsenic Cadmium Chromium Lead
Kidney	Arsenic **Cadmium** Chromium Lead
Reproductive system: male	Lead Cadmium Chromium
Hematopoetic system (blood)	Arsenic **Lead** Cadmium Chromium
Cancer (skin, bladder, liver, kidney)	Arsenic

***Bold** indicates critical effect organs/systems.*

Joint Toxicity: Pairwise Interactions

Metal Interactions	Blood	Kidney	Neurologic	Male Reproductive	Skin	Cardio-vascular
Higher than additive: Synergism			As + Pb Cd+Pb	Cd + Pb	Cr + As	As + Cr
Additive		As + Cd				Cd + Pb
Lower than additive: Antagonism	As + Cd As + Pb Cd + Pb	As + Cd As + Cr As + Pb Cd + Pb		As + Cd		

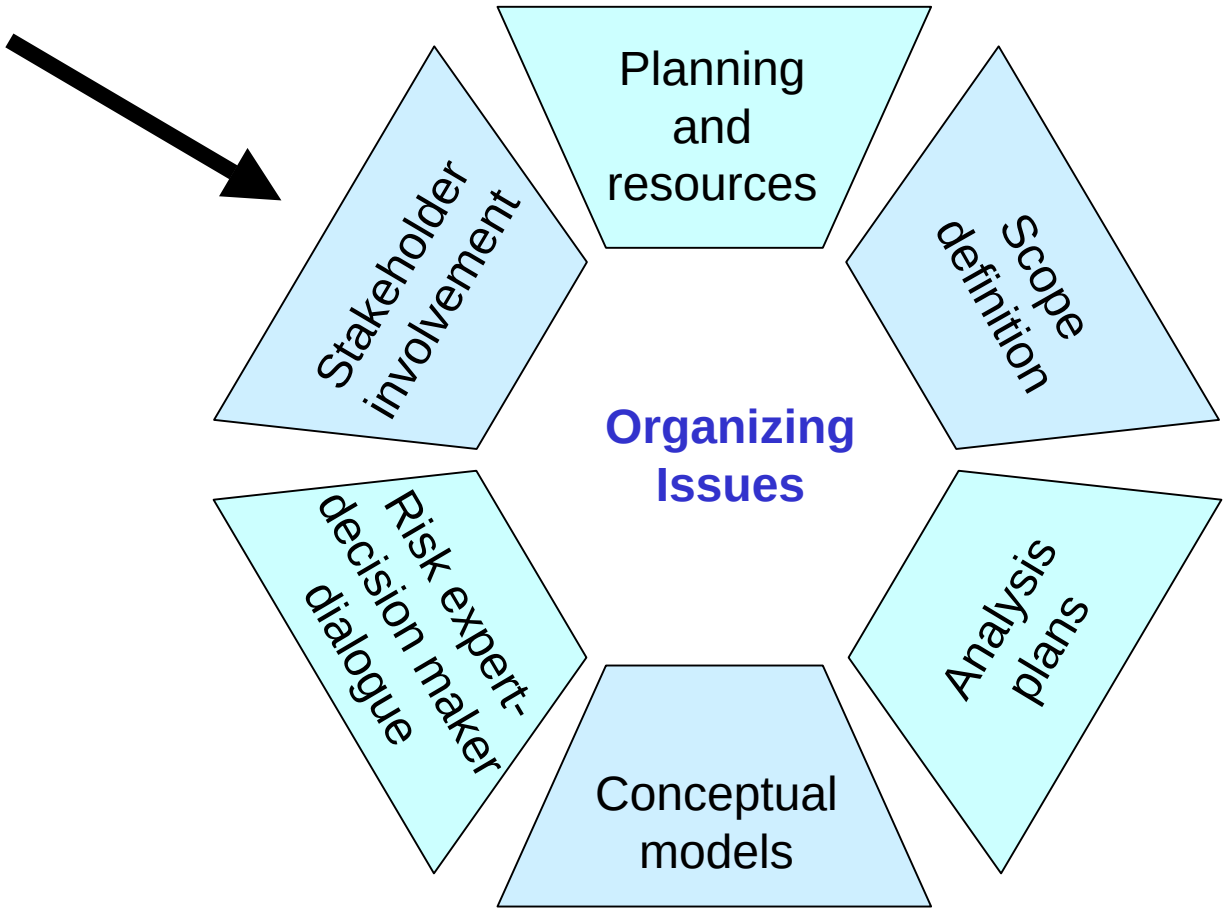
Planning and Scoping (adapted from U.S. EPA, 2002)



Key Planning and Scoping Questions	
What is the concern?	Who needs to be involved?
Why is there a problem?	What is the scope? What are the alternatives?
How is it evaluated?	*(Source: U.S. EPA, 2002)*

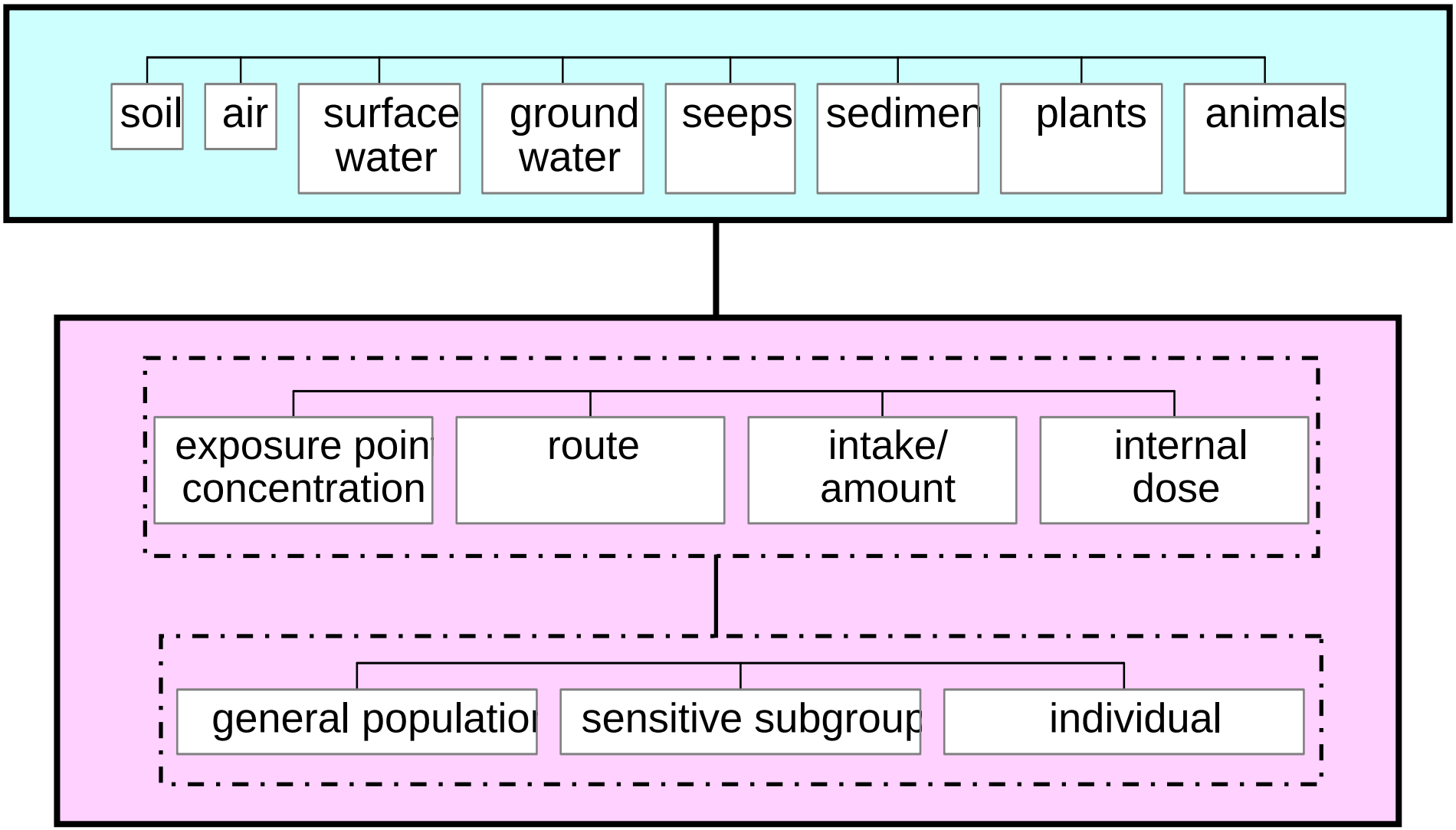
How can we best inform a choice among alternatives?

Planning and Scoping



Community Involvement: A 2-Way Street

Participant Interaction Suggestions	
Frequency	Ensure capture of initial cumulative risk issues -- regularly disseminate information
Rotating locations	Offer many accessible/familiar venues to promote input from many different people
Alternate times	Accommodate different participant schedules
One-on-ones	Regular interactions with those unable to attend
Electronic	Project website


soil
air
surface water
ground water
seeps
sedimen
plants
animals
exposure poin concentration
route
intake/ amount
internal dose
general populatio
sensitive subgroup
individual

Stakeholders Critical to Assessment

Example Stakeholder Technical Input	
Knowledge	*Use for Cumulative Risk Assessment*
Past disposal practices	Characterize chemicals and locations; input to fate and exposure models
Well locations and depths	Define nearby exposure points and nodes for groundwater model
Activity/use patterns	Identify realistic exposure factors

Document Organization: Chapters

1 - Introduction

2 - Planning and scoping

3 - Problem formulation

4 - Exposure assessment

5 - Key mixtures toxicity concepts

6 - Cumulative risk characterization step

7 - Communicating cumulative risk information

8 - Summary and targeted research

Document Organization: Appendices

A - Resources to conduct cumulative risk assessments

B - Organizing primary toxicity info

C - Communicating toxic interactions info

D & E - Case studies

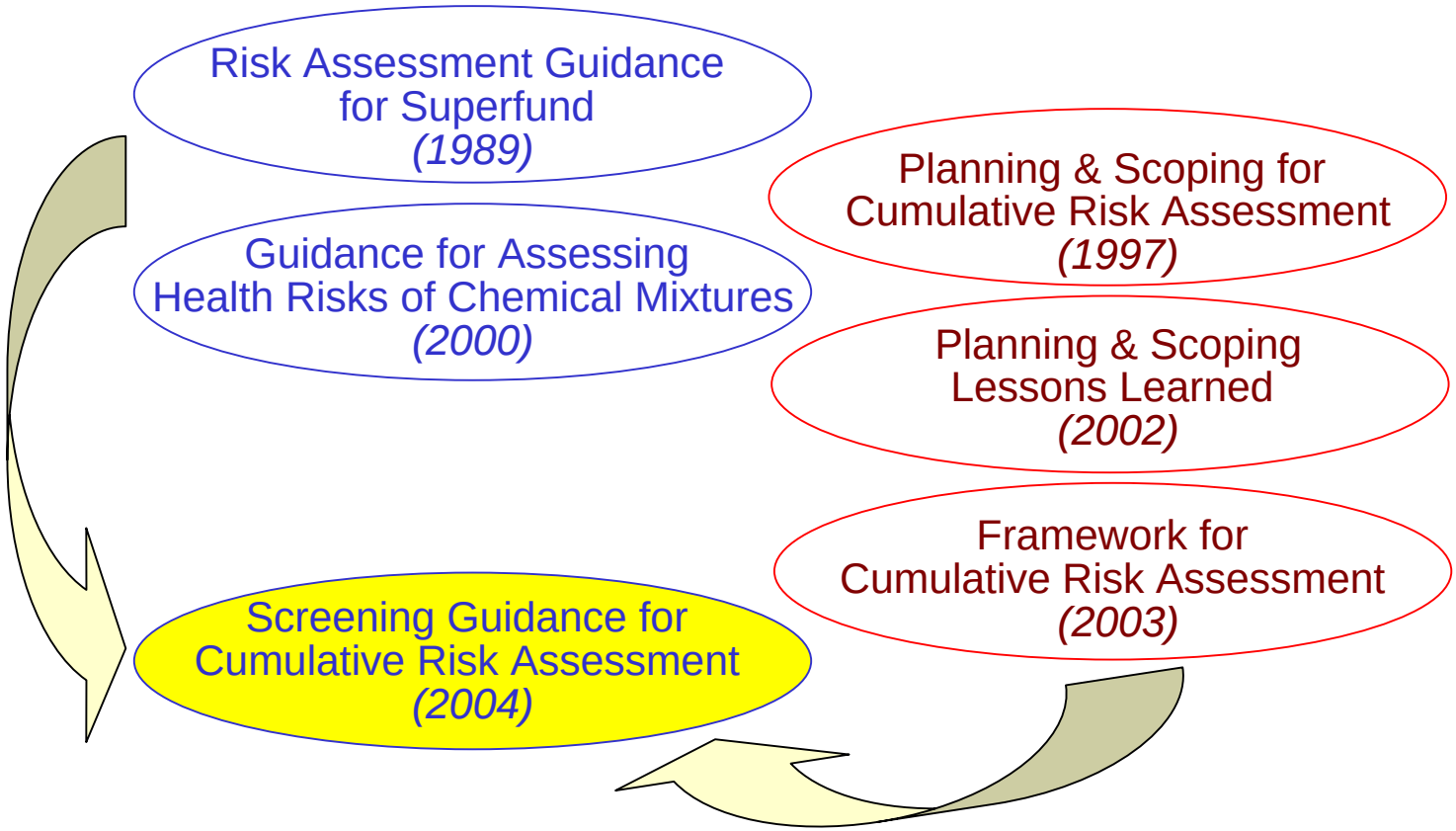
F - Concepts for joint toxicity of multiple chemicals

What Are Some Bottom Lines?

- **Spending limited resources wisely**
  Translating science to risk guidance/policy in face of perceptions: inaccuracy and overkill?
  - "True" risks reflect all stressors and factors
  - Over-protective if uncertain
  - Addressing interactions potentially more realistic

- **Equity in communities**
  - Traditional risk assessments based on sources ignore multiple impacts on same person
  - Less access to health care, greater potential risk

Related EPA Efforts



Key EPA Foundations of Screening Guidance

(to assess cumulative health risks at contaminated sites)

Next Steps

- **EPA's Risk Assessment Forum**
  - Case studies
  - Issue papers
  - Formal and detailed guidelines for conducting cumulative risk assessments (Expected 2012)
    - Stressors other than chemical (e.g., noise)
    - Non-conventional issues (e.g., healthcare access)

- **Methods coupling environmental public health data with epidemiological information related to multiple chemicals**

- **Improved decision frameworks**
  - Assess "ripples" of cumulative health risk actions
  - Cultural impacts (e.g., endpoint may be driver or influence remediation options)
  - Economic impacts (e.g., changes property values, loss of jobs)
  - Environmental/Ecological effects along with human health